

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: BENICAR (OLMESARTAN)	*	MDL 2606
PRODUCTS LIABILITY LITIGATION	*	
	*	
THIS DOCUMENT RELATES TO	*	JUDGE ROBERT B. KUGLER
ALL CASES	*	
	*	MAG. JUDGE JOEL SCHNEIDER

**PROPOSED JOINT AGENDA AND REPORT
FOR 28 OCTOBER 2015 STATUS CONFERENCE**

A. 10:00 AM Session before Judge Schneider

1. Document Production Schedule

DEFENDANTS' POSITION:

Defendants estimate a 16-month schedule is required to produce these categories of documents: (1) documents from the 86 Daiichi U.S. and Forest custodians; (2) documents from the 54 Japan custodians; and (3) the non-custodial categories of documents (as detailed below). This schedule, which estimates production at a rate of two-to-four million pages per month, is ambitious but achievable. This production rate is higher than the other MDLs referenced during the October 16 telephone conference with the Court. The enormous volume of documents is based on Plaintiffs' growing and ever-changing demands relating to custodians (presently 216 custodians, excluding the 58 newly proposed Japanese custodians and another dozen or more newly proposed U.S. custodians), search terms (606 variations), non-custodial documents, and systems. One hundred English language and 50 Japanese language reviewers are working full time on this body of documents. Defendants also are collecting documents and data from the 76

newly identified Daiichi U.S. and Forest custodians, and will provide a reasonable estimate relating to productions once the volume of documents is known.

To date, Defendants have produced approximately eight million pages of documents in discovery. Based on the Court orders and Plaintiffs' demands, in the next 120 days Defendants plan to produce over 10 million additional pages of documents in the following categories: rolling production for 216 custodians; 9,500 adverse event reports; documents relevant to the DOJ subpoena; foreign regulatory documents; DSC development files, DSC complaint files, DSC regulatory submissions; 2010 ROADMAP study trial master file documents (approximately 1.5 million pages of paper documents which are located in Germany); file share data; system data; DFS documents; and other categories of documents. *See* Letters to Judge Schneider, October 14, 2015 and October 21, 2015. The parties met and conferred on October 19, 22, and 26, 2015, and Plaintiffs refused to reduce the requests, reduce the custodians, or eliminate search terms. Around 4:30 p.m. on October 22, plaintiffs finally provided a list of custodians they wish to prioritize. This won't reduce the time discovery takes, it will simply give plaintiffs what they want most sooner. Given the facts here, the time for document production is reasonable if not aggressive. The process takes so long because the plaintiffs want so much, not because of anything the defendants are doing "for their own purposes".

PLAINTIFFS' POSITION:

Plaintiffs have attempted to meet and confer with the Defendants regarding the production of discovery, but Defendants have refused to provide important information to the Plaintiffs, making it impossible for Plaintiffs to fully understand the true status of the Defendants' document productions. Defendants have not justified their repeated demands that Plaintiffs agree to modify the agreed search terms, or to forego important discovery. In fact, it

appears that the primary reason that the custodial productions are not being produced more quickly is the Defendants' reviews for their own purposes, including relevancy reviews and coding of documents for their own litigation purposes. Plaintiffs believe that the Defendants can produce documents far more efficiently and quickly than predicted, if they are ordered to forego steps that are not productive and to meet aggressive deadlines.

Notwithstanding, Plaintiffs have agreed to prioritize the production of custodial documents, providing a list of 27 custodians to be prioritized from the initial lists of 86 US custodians and 55 Japanese custodians. Plaintiffs have also agreed to staged productions of documents from the 75 additional US custodians, with the documents from the email servers to be produced initially, and the documents from the laptops and paper documents to be produced in a secondary phase within a reasonable period following the initial phase of production.

Plaintiffs are also working to prioritize the production of non-custodial files and documents, including for example sharepoints and databases, and have identified specific databases/applications that are presumably in line for production and requested they be produced on a priority basis.

In further efforts to prioritize discovery, Plaintiffs have requested identification and production of a discrete set of adverse event reports and source files referenced in a November, 2009 email chain regarding internal concern over a number of "Celiac" cases, and information regarding the ROADMAP Trial Master File to expedite discovery of the critical features such as the patient level case report forms ("CRF's"), which have been requested, draft and final protocols and study reports, data compilations and analyses, tables, and other critical features.

Plaintiffs expect that the parties will continue to exchange proposals and information prior to the hearing.

2. Newly Identified Japan Custodians

DEFENDANTS' POSITION:

Plaintiffs identified 58 new Daiichi Sankyo Company, Limited (DSC) Japan custodians on October 19, 2015, essentially doubling the current list of 54 DSC custodians. This would bring the number of total custodians in this litigation to 275 people. This is not a “reasonable number” in accordance with Court’s instruction at the October 16, 2015 teleconference. Moreover, Plaintiffs provided no information as to where these additional 58 names came from or citations to the organizational chart, shifting the burden to Defendants to locate and provide a basis to dispute the new custodian requests. Plaintiffs should be required to narrow their list of additional Japan custodians in accordance with the Court’s prior instructions, the proportionality principles of Fed. R. Civ. P. 26(b), and the guidelines of the Sedona Conference on Proportionality in Electronic Discovery.

PLAINTIFFS' POSITION:

Plaintiffs carefully reviewed the records available to us, and information from other sources, to compile a list of 58 potential additional custodians to be searched from Daiichi Japan. This number is far less than what was presented in connection with Daiichi US. The letter serving the list asked the Defendants to advise us as to any custodians they had questions or concerns about, with the expectation that we would meet and confer as necessary, and reach agreement on the list. Defendants refused to discuss this issue, instead demanding that Plaintiffs serve a written explanation of the basis for including each potential custodian. Plaintiffs advised that we remain ready to have a discussion in order to facilitate agreement, and we remain willing to do so. A call took place on October 27, 2015 in the afternoon. We will be prepared to engage in a detailed discussion with the Court and counsel at the hearing.

3. Deposition Protocol and Deposition Plan

DEFENDANTS' POSITION:

Defendants sent Plaintiffs a proposed Deposition Protocol on October 6, 2015. On October 16, 2015, Plaintiffs returned a redline version of the Protocol. The parties will meet and confer on plaintiffs' proposed changes to the Protocol and report to the Court on the areas of disagreement. There are a number of important and fundamental areas of disagreement between the parties that will require a briefing schedule.

As of October 22, Plaintiffs have not yet provided Defendants with a Proposed Deposition Plan as directed by the Court. It is Defendants' view that the number of depositions should be limited to 5 individual depositions and 5 30(b)(6) depositions per each of the three defendant groups (U.S. Daiichi, Japan Daiichi and Forest). Defendants do not agree with Plaintiffs' suggestion for scheduling. The traditional method which has worked without a hitch in all other MDLs should be employed here – the plaintiffs supply a list of the people they want to depose 60 to 90 days before the deposition period, and the defendants offer dates for those depositions.

PLAINTIFFS' POSITION:

The parties conferred on October 26, 2015, reaching agreement on certain contested provisions. A number of provisions will need to be determined by the Court. For example, Plaintiffs included language to ensure that counsel and witnesses will cooperate during depositions and eliminate obstruction and delay. Plaintiffs disagree with Defendants' proposal to prematurely set limits, especially the unreasonably small limits provided, on the number of corporate witness depositions. Plaintiffs do not see the need for briefing.

Based on the assumption that Defendants will produce documents at a rapid and steady pace, Plaintiffs believe that depositions of corporate witnesses should begin on February 1, 2016, with the parties to set aside dates now for the depositions, with the deponents to be assigned to the pre-set dates as discovery progresses. A schedule for expert depositions will be dependent on the deadlines to be set for expert reports.

4. Diversity Jurisdiction

DEFENDANTS' POSITION:

Plaintiffs who reside in New Jersey continue to file their complaints in the MDL where no diversity exists. These plaintiffs should be required to dismiss their Complaints and re-file in an appropriate venue.

Case No.	Plaintiff name	Plaintiff counsel	Town and State of Residency
1:15-cv-05442	Ashley Arguelles	Golomb and Honik	Passaic, NJ
1:15-cv-06588	Constance Douglass	Golomb and Honik	Jersey City, NJ
1:15-cv-04442	Kevin Graham	McEwen Law Firm, LTD	Williamstown, NJ
1:15-cv-06108	Raymond Romsdahl	Orlando Firm, P.C.	Lambertville, NJ
1:15-cv-04410	Lourdes Vigier	McEwen Law Firm, LTD	Scotch Plains, NJ
1:15-cv-06755	Sharon Leone-Deitch,	Golomb and Honik, P.C.	Ventnor, NJ
1:15-cv-06698	Irma Marrero	Golomb and Honik, P.C.	Newark, NJ

The Golomb & Honik law firm has agreed to dismiss their four cases which lack diversity jurisdiction and refile them in New Jersey State court but have not yet done so and Defendants have not heard from the other firms who were notified of the lack of diversity early this month.

PLAINTIFFS' POSITION:

Plaintiffs' leadership has notified all Plaintiffs' counsel of this issue.

5. Objections to Plaintiff Fact Sheets

Notwithstanding Plaintiffs' lead counsels' representations, Defendants are receiving increasing numbers of Plaintiff Fact Sheets with objections to questions. For example, in a Fact Sheet received from the Abbott Law Group, in response to the question "Do you allege sprue-like enteropathy?", plaintiff did not answer and instead stated "Plaintiff objects insofar as this question is vague and seeks a medical expert opinion, and further reserves the right to supplement the answer based on subsequent discovery." As Plaintiffs and the Court have agreed, a plaintiff cannot object to Plaintiff Fact Sheet questions and all questions must be answered. Defendants respectfully request entry of an order stating that no objections are permitted and all questions must be answered.

6. Defendants' PFS Deficiency Notices

Defendants' Position:

"Core deficiency" letters are sent in cases which are lacking the basic information necessary to prepare a DFS. Not a single plaintiff has challenged a core deficiency letter. Defendants should not have to go to the expense and time of producing a DFS where the plaintiff has not demonstrated that he or she has used the Product or had the event, as the Court Order

recognizes, nor can a DFS be completed without basic information about the prescribing physician. Defendants will be prepared to discuss this issue further with the Court if necessary.

Plaintiffs' Position:

Defendants have been serving deficiency notices, stating that a Plaintiff has not adequately claimed or documented sprue-like enteropathy. These criticisms are misplaced in many cases, since the plaintiffs have in those cases alleged sprue-like enteropathy, and documented clinical symptoms such as diarrhea and abdominal pain, which are claimed to be due to the intestinal condition. Defendants also state that they reserve additional deficiencies for later. These practices should stop, with only substantial deficiencies raised, and with no reservation of deficiency notices for a later date, so that Defendants will timely serve their DFS's. Plaintiffs also see this tactic as an effort by the defense to artificially narrow the scope of cases in this MDL, despite the fact that this Court has previously stated that the definition of cases in this MDL is broad.

Plaintiffs' leadership has been informed that deficiency letters have been challenged.

6. Production Log Issue

Defendants' Position:

The weekly production index provides all information required by the ESI Protocol, specifically: "the date, Bates ranges, source of documents for each Bates range (e.g., custodian, database), document or discovery request responded to, and date of withdrawal of protected designation and replacement of document or image with no protected designation, where applicable."

To the extent that Plaintiffs are now again demanding that Defendants prepare a document-by-document source identification index, such an undertaking is overly burdensome, expensive, time consuming, and outside Defendants' obligations under the ESI Protocol. Plaintiffs can identify this information themselves using the agreed-upon 68 metadata fields that Plaintiffs demanded for each individual document, including CUSTODIAN, DUPLICATE_CUSTODIANS and AUTHOR.

Defendants have repeatedly told Plaintiffs, as far back as December 2014 when negotiations related to the ESI protocol began, and as recently as October 22, 2015, that they would not provide a document-by-document source identification index.

Plaintiffs' Position:

The ESI Protocol provides for the Defendants to provide a production log, updated with every production. Among other things, the log is supposed to set forth the source of the documents identified, for example which custodian, sharepoint, database, or other specific source the documents came from. Plaintiffs are not requesting a document by document index, since documents are/should be produced in groups for particular custodians, databases, and other sources. Instead, the Defendants are simply identifying the source in generic terms, i.e. "custodial documents", "custodial electronic mail", "Marketing." This is in violation of the ESI Protocol, and fails to provide Plaintiffs with important information both to prioritize and assign documents for review, and to have the detailed information regarding each production that was negotiated and intended. Plaintiffs request that this deficiency be remedied immediately and on a going forward basis.

B. 2:00 PM Session before Judge Kugler and Judge Schneider

1. Report on Docket.

Defendants' Position:

There were 1,118 complaints on file with the clerk's office as of October 26, , 2015, and the U.S. Daiichi defendants had been served with 656 complaints.

2. State Court Litigation.

There are currently 65 cases pending in the New Jersey MCL. Judge Nelson C. Johnson, J.S.C. has scheduled a telephone conference for November 12, 2015 at 11:00 A.M.

3. Plaintiff Fact Sheets.

Defendants' Position:

As of October 23, 2015, 270 PFSs have been received. Of the 63 which have gone through the core deficiency review process, approximately one third do not have medical records showing plaintiff had sprue like enteropathy or something close and/or do not have pharmacy records showing that an olmesartan medicine was dispensed. At the request of Mr. Slater and Mr. Coffin at the last conference, they are now copied on all the core deficiency letters. Further, Mr. Slater and Mr. Coffin have their own mail box set up to receive copies of all PFSs; Defense Counsel is aware of this because some Plaintiff lawyers copy the database on service e-mails.

Plaintiffs' Position:

Plaintiffs' leadership has not seen the PFS responses alluded to by Defendants. Plaintiffs are concerned that Defendants are not reading the PFS requests in a reasonable fashion, and are seeking to create issues to delay the service of DFS's. For example, it is difficult to interpret what the defense means in referencing "sprue like enteropathy or something close." Plaintiffs' lead counsel do not read the PFS's as they are submitted to the PSC repository.

4. Bellwether Selection Process

The parties have submitted separate orders for the Bellwether Selection Processes. The parties met and conferred on this issue on October 15 and 26, 2015. The parties have submitted competing proposals with this Agenda. (Plaintiffs' proposal as Exhibit 1, Defendants' proposal as Exhibit 2).

5. Service on Daiichi Japan

Defendants' Position:

Service by e-mail is not required by any rule, law or treaty and this is the first litigation we are aware of which has tried it. Defendants decline to extend this to the Japanese defendant, having already relieved Plaintiffs of their obligations under the Hague Convention. Defendants further object to the entry of a Court order with instructions on how to serve the Japanese defendant.

Plaintiffs' Position:

Plaintiffs have asked Defendants to agree to service on Daiichi Japan in accordance with the recent Order providing for email service on Daiichi US, and Forest. Defendants previously agreed that service upon Daiichi Japan via certified mail will be accepted, once service was made via Hague Convention in one case, which has been completed. Daiichi Japan has refused to now accept service via email, in accordance with the procedure now in place for the other defendants, without explanation. This step would simplify service of process, through a uniform process for all Defendants, and allow the cases to move forward more efficiently. In either case, Plaintiffs request entry of an Order so that counsel will know the proper method of service, and address.

6. Medical Records

The parties are meeting and conferring on medical record collection processes.

7. Dismissals Without Prejudice

Defendants' Position:

All dismissals of improvidently filed cases should be with prejudice. Defendants object to the plaintiffs' process which simply leads to "red shirting" of cases.

Plaintiffs' Position:

Plaintiffs initiated discussions with Defendants regarding cases that Plaintiffs may want to voluntarily dismiss. In order to avoid motion practice, Plaintiffs proposed a procedure wherein a

plaintiff may voluntarily dismiss a case without prejudice. This would streamline the litigation.

To date, Defendants have not agreed.

8. **Entry of Case Management Order Implementing DFS**

Defendants' Position:

Defendants understand that the Court does not view the implementation order as being necessary.

Plaintiffs' Position:

The plaintiffs request entry of the case management order and attached Defendants Fact Sheet submitted to the Court as agreed, implementing the DFS. This is needed so that all counsel can reference the Order and the form of DFS, and this can be placed on the Court's website.

Dated: October 27, 2015

Respectfully Submitted,

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